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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/843,918	04/30/2001	Changsheng Liu	9046-022	9883
26171	7590	09/21/2004	EXAMINER	
FISH & RICHARDSON P.C. 1425 K STREET, N.W. 11TH FLOOR WASHINGTON, DC 20005-3500			STARSIAK, JOHN S	
			ART UNIT	PAPER NUMBER
			1753	

DATE MAILED: 09/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/843,918	Applicant(s) LIU ET AL.	
	Examiner John S. Starsiak Jr.	Art Unit 1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 Decemeber 2001.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 Decemeber 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>4/30/01</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 7 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 7 recites a long list of desirable properties of the electrophoresis separation medium which are the result of the "at least one secondary comonomer". However, the specification provides no guidelines for achieving these results. Although the specification provides a long list of potential second comonomers, the specification fails to identify which second comonomers will produce a particular desirable property.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 recites, "The method of claim 1...". Claim 1 is directed to "an electrophoresis separation medium".

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3-5, 7, 8, 10-12, 14, 16-18, 20, and 22-24 rejected under 35 U.S.C. 102(b) as being clearly anticipated by Sawada & Jinno (Electrophoresis 1997, 18, 2030-2035).

For purposes of rejection, the term “gel” includes entangled polymers since the applicant in the specification defines “random, linear copolymers” as “a copolymer that is made up of more than one monomer, in which different monomer units are distributed along a copolymer in no specific pattern, and the copolymer **is not crosslinked** with other copolymers” and none of the gels described in the examples is crosslinked. The portions of independent claims 1, 8, 14, and 20 which are directed to the composition of the “gel matrix” reads on Sawada & Jinno [Abstract]: “Noncross-linked acrylamide (AA) – N-isopropylacrylamide (IPAAm) copolymers have been used as a buffer additive in

Art Unit: 1753

capillary electrophoretic separation of structurally similar small solutes. Regarding the recitation that the copolymer is a “random, linear copolymer”, while

Sawada & Jinno do not explicitly state that the copolymer is random and linear, this fact can be determined from the description of the copolymer synthesis, i.e. [page 2032, right hand column]: “...the capillaries were filled with the buffer solution containing AA, IPAAm, APS, and TEMED. These capillaries were filled the polymerization solution overnight while both ends of were dipped into the same polymerization solution.”.

Regarding the “ratio of reactivity” recited in claim 3, 10, 16, and 22, this particular is considered to be inherent in the copolymers of Sawada & Jinno because of the structural similarity between the secondary polymer of Sawada & Jenno, i.e. N-isopropylacrylamide and the specific copolymer recited in the claims of the present application, i.e. dimethylacrylamide. Regarding the “pH of the buffer” recited in claims 4, 11, 17, and 23 and the “aqueous medium having a pH...” recited in claim 8, these particulars read on Sawada & Jinno since the pH of the buffer in Swada & Jinno is 8.3 (see information under Figure 1). Regarding claim 7, this claim reads on because Sawada & Jinno teaches that the secondary copolymer ( N-isopropylacrylamide) imparts hydrophobicity to the copolymer [page 2030, right hand column]: “The copolymer prepared in this study has hydrophobic ligands (isopropyl groups) in its polymer chain.”. Although Sawada & Jinno do not explicitly disclose the viscosity of their linear polymers, the “viscosity” range recited in claims 5, 12, 18, and 24 is considered to be inherent in Sawada & Jinno because of the structural similarities between the two polymers and because the two polymers are used for the same purpose. Regarding the separation of

“mixture of biological molecules” recited in claim 20, this particular reads on the separation of a mixture of dansylated amino acids of Sawada & Jinno [page 2035, left hand column and figure 6].

Claims 1, 6, 8, 13, 14, 19, 20, 25 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Sawada & Jinno (Analyst, July 1998, Vol. 123, pp. 1471-1476). This article is very similar to the article of Sawada & Jinno in Electrophoresis. Hence, independent claims 1, 8, 14, and 20 read in this article (see Abstract). In addition, claims 6, 13, 19, and 25 which recite a range of molecular weights for the copolymer read the molecular weights shown in Table 3 of Sawada and Jinno.

Claims 1, 2, 3, 5, 8, 9, 10, 12 and 26 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Cottrell et al.

All the particulars of the gel matrix recited in claims 2, 9, and 26 read on the copolymer solutions of Cottrell et al. Specifically, Cottrell et al teaches [col. 1, lines 21-23]: “The present invention is directed to linear and cross-linked copolymers of acrylamide and N,N-dimethylacrylamide...”. Regarding the recitation in claims 1 and 8 that the copolymer is random Cottrell et al. teaches [col. 1, lines 44 & 45]: “the distribution of NNDMA and AM in the polymer chain is random. The characterizations of the invention as “an electrophoresis separation medium” (claim 1) and “a method of preparing an electrophoresis separation medium (claim 8) are considered to be recitations of intended use. Hence, they are given no weight. The range of the “ratio of

reactivity" recited in claims 3 and 10 is inherent to the copolymer of Cottrell because the two monomers are those in the exemplary copolymer recited in the claims. The "pH" range of the aqueous medium recited in claim 8 is considered to be inherent in Cottrell et al. because the composition of the reaction mixture of Cottrell et al. contains not species which would cause the reaction mixture to have either a high or low pH (outside the range of 5-11). Regarding the viscosity recited in claims 5 and 12 see the table of Cottrell et al. [col.5, lines 44-52].

Claims 1, 2, 6, and 26 are rejected under 35 U.S.C. 102(e) as being anticipated by Takano et al.

The composition of the copolymer recited in claims 1,2, and 26 reads on Takano et al. [col. 8, lines 23-25]: "For example,... a copolymer of acrylamide and N,N-dimethylacrylamide...are included." The "molecular weight" range recited in claim 6 reads on the range of Takano et al. [Abstract]: "a weight average molecular weight ranging from 20,000 to 250,000..."

Claim 27 is rejected under 35 U.S.C. 102(e) as being clearly anticipated by Hooper et al. (5,885,432).

The copolymer recited in claim 27 reads on the copolymer comprising N,N'-dimethylacrylamide and N,N'-diethylacrylamide described in Example 1 (column 9 of Hooper et al.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 8, 9, 15 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over either article of Sawada & Jinno in view of either Zhang et al.

For details of the articles of Sawada & Jinno see the rejections above. The only difference between the claims and the articles of Sawada & Jinno is that in the claims the copolymer consists of acrylamide and dimethylacrylamide and in Sawada and Jinno the copolymer consists of acrylamide and isopropylacrylamide. In both of the articles of Sanaka & Jinno the reason isopropylacrylamide was used was to introduce hydrophobic groups into the separation medium, e.g. Sawada & Jinno (Electrophoresis) [Abstract]: "the migration behavior of small molecules in solutions of the copolymers containing hydrophobic groups was different from the separation in a free solution or in polyacrylamide solution.". Zhang et al. teaches that dimethylacrylamide contains hydrophobic groups. Zhang et al. teaches [col. 2, line 19]: "DMA (dimethylacrylamide) is very hydrophobic...". It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute dimethylacrylamide for the isopropylacrylamide of Sawada & Jinno, because it is known in the art that both of these monomers contain hydrophobic groups.

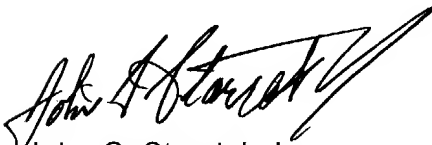


**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Starsiak Jr. whose telephone number is (571) 272-1346. The examiner can normally be reached on Monday to Friday from 7:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen, can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



John S. Starsiak Jr.

14 September 2004

Application/Control Number: 09/843,918

Page 9

Art Unit: 1753

A handwritten signature in black ink, appearing to read 'Nam Nguyen', is written over the printed name and title.

NAM NGUYEN  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1700